Complete Summary

GUIDELINE TITLE

KDOQI clinical practice guidelines and clinical practice recommendations for diabetes and chronic kidney disease.

BIBLIOGRAPHIC SOURCE(S)

KDOQI. KDOQI clinical practice guidelines and clinical practice recommendations for diabetes and chronic kidney disease. Am J Kidney Dis 2007 Feb;49(2 Suppl 2):S12-154. [598 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Combination of chronic kidney disease (CKD) and diabetes mellitus

Note: The general treatment of diabetes is beyond the scope of this guideline

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Risk Assessment
Screening

CLINICAL SPECIALTY

Cardiology
Endocrinology
Family Practice
Geriatrics
Internal Medicine
Nephrology
Nursing
Nutrition
Obstetrics and Gynecology
Pediatrics

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Dietitians
Health Care Providers
Nurses
Pharmacists
Physician Assistants
Physicians
Social Workers

GUIDELINE OBJECTIVE(S)

To improve outcomes in patients with diabetes and CKD by providing strategies for the diagnosis and management of CKD in the setting of diabetes and for the management of diabetes in the setting of CKD

TARGET POPULATION

Patients with both diabetes mellitus and chronic kidney disease (CKD) stages 1 to 5, including dialysis and transplant patients

Note: Consideration is given to the diagnosis, impact, and management of diabetes and CKD in children, adults, the elderly, pregnant women, and different racial and ethnic groups.

INTERVENTIONS AND PRACTICES CONSIDERED

1. Screening and diagnosis of diabetic kidney disease (DKD)
    - Investigation into the underlying cause(s) of chronic kidney disease (CKD)
    - Screening tests for DKD including urinary albumin-creatinine ratio (ACR) in a spot urine sample, serum creatinine and estimation of glomerular filtration rate (GFR)
    - Confirmation of elevated ACR as indicated with additional first-void specimens
    - Diagnostic criteria for DKD

2. Management of hyperglycemia and general diabetes care in CKD (target hemoglobin A_{1c} [HbA_{1c}])
3. Management of hypertension in diabetes and CKD
    - Angiotensin-converting enzyme [ACE] inhibitor or an angiotensin receptor blocker [ARB], usually in combination with a diuretic
    - Target blood pressure
4. Management of dyslipidemia in diabetes and CKD
    - Target low-density lipoprotein cholesterol (LDL-C)
    - Statin as appropriate
5. Nutritional management (dietary modifications, such as target dietary protein intake) in diabetes and CKD
6. Management of albuminuria in normotensive patients with diabetes and albuminuria as a surrogate marker
    - Treatment with ACE inhibitor or an ARB
    - Albuminuria reduction as a treatment target
7. Multifaceted approach to intervention in diabetes and CKD
    - Concurrent management of multiple risk factors
    - Instruction in healthy behaviors
    - Treatments to reduce risk factors
    - Target body mass index (BMI)
8. Management of diabetes and CKD in special populations
    - Identifying populations at greatest risk
    - Special considerations in the treatment of children, adolescents, and the elderly
    - Population-based interventions
    - Co-management by specialists
    - Treatment of DKD with renin-angiotensin system (RAS) inhibitors before pregnancy
    - Insulin to control hyperglycemia if pharmacological therapy is necessary in pregnant women with diabetes and CKD
9. Behavioral self-management in diabetes and CKD

MAJOR OUTCOMES CONSIDERED

Patient outcomes (death, chronic kidney disease [CKD] progression, albuminuria, glucose levels)

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Literature Search

The Work Group members developed specific questions with regards to predictors and interventions related to specific outcomes. Search strategies were developed according to specific study topics, study design, and years of publication. Studies for the literature review were identified through MEDLINE searches of English

language literature of human studies from January 1990 to December 2003. Selective updates were performed through May 2005. Broad MeSH (medical subject heading) terms and text words were used so that searches were both general in scope for high sensitivity in identification of pertinent literature and specific to preliminary topics selected by the Work Groups. The searches were also supplemented by articles identified by Work Group members through August 2005.

The principal kidney-related search terms used included: kidney, renal, kidney disease, albuminuria, proteinuria, hematuria, and hyperfiltration. Principal diabetes-related terms included: diabetes mellitus, hyperglycemia, retinopathy, and pregnancy in diabetes.

Only full journal articles of original data were included. Editorials, letters, abstracts, and unpublished reports were not included. Selected review articles, however, were included for background material. A separate search for systematic reviews of health education in diabetes was conducted for the behavioral management recommendation.

MEDLINE search results were screened by members of the Evidence Review Team for relevance using predefined eligibility criteria. Retrieved articles were screened by the Evidence Review Team. Potentially relevant studies were sent to Work Group members for rescreening and data extraction. Domain experts made the final decision for inclusion or exclusion of all articles.

While the literature searches were intended to be comprehensive, they were not exhaustive. MEDLINE was the only database searched, and searches were limited to English language publications. Hand searches of journals were not performed, and review articles and textbook chapters were not systematically searched. However, important studies known to the domain experts that were missed by the literature search were included in the review. No meta-analyses were performed.

Literature Yield

For the primary literature topics, the literature searches yielded 11,378 citations. Of these, 765 articles were retrieved in full. An additional 57 studies were added by Work Group members. From all 822 articles, 250 were extracted and included. Of these, 142 studies are included in Summary Tables. A supplemental search for systematic reviews of diabetes and health education yielded 901 citations, of which 10 systematic reviews were summarized.

NUMBER OF SOURCE DOCUMENTS

142 studies are included in Summary Tables. 10 systematic reviews were summarized.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

The strength of evidence was graded using a rating system that primarily takes into account: (1) the methodological quality of the studies; (2) whether the studies were carried out in the target population (i.e., patients with chronic kidney disease and diabetes, or in other populations) and (3) whether the studies examined health outcomes directly, or examined surrogate measures for those outcomes (e.g., reducing death or improving albuminuria). These 3 separate study characteristics were combined to provide a preliminary strength of evidence provided by pertinent studies. In addition, aspects of the GRADE recommendations for grading the quality of evidence and the strength of recommendations were incorporated to determine a final strength of evidence.

		Methodological Quality		
Outcome	Population	Well Designed and Analyzed (little, if any, potential bias)	Some Problems in Design and/or Analysis (some potential bias)	Poorly Designed and/or Analyzed (large potential bias)
Health outcome(s)	Target population	Strong[a]	Moderately strong[b]	Weak[h]
Health outcome(s)	Other than the target population	Moderately strong[c]	Moderately strong[d]	Weak[h]
Surrogate measure for health outcome(s)	Target population	Moderately strong[e]	Weak[f]	Weak[h]
Surrogate measure for health outcome(s)	Other than the target population	Weak[g]	Weak[g]	Weak[g,h]

Strong: [a]Evidence includes results from well-designed, well-conducted study/studies in the target population that directly assess effects on health outcomes.

Moderately Strong: [b]Evidence is sufficient to determine effects on health outcomes in the target population, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies; OR [c]evidence is from a population other than the target population, but from well-designed, well-conducted studies; OR [d]evidence is from studies with some problems in design and/or analysis; [e]OR evidence is from well-designed, well-conducted studies or surrogate endpoints for efficacy and/or safety in the target population.

Weak: [f]Evidence is insufficient to assess the effects on net health outcomes because it is from studies with some problems in design and/or analysis on surrogate endpoints for efficacy and/or safety in the target population; OR [g]the evidence is only for surrogate measures in a population other than the target population; OR [h]the evidence is from studies that are poorly designed and/or analyzed.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Generation of Data Extraction Forms

Data extraction forms were designed to capture information on various aspects of the primary articles. Forms for all topics included study setting and demographics, eligibility criteria, severity of kidney disease, type of diabetes, numbers of subjects, study design, study funding source, comorbid conditions, descriptions of relevant risk factors or interventions, description of outcomes, statistical methods, results, study quality based on criteria appropriate for each study design (see below), study applicability (see below), and sections for comments and assessment of biases. Training of the Work Group members to extract data from primary articles occurred at face-to-face meetings, supplemented by e-mails and teleconferences.

Generation of Evidence Tables

The Evidence Review Team condensed the information from the data extraction forms into evidence tables, which summarized individual studies. These tables were created for the Work Group members to assist them with review of the evidence and are not included in the guidelines. All Work Group members (within each topic) received copies of all extracted articles and all evidence tables. During the development of the evidence tables, the Evidence Review Team checked the data extraction for accuracy and rescreened the accepted articles to verify that each of them met the initial screening criteria determined by the Work Group.

Format for Summary Tables

Summary tables describe the studies according to 4 dimensions: study size and follow-up duration, applicability or generalizability, results, and methodological quality. Within each table, the studies are first grouped by outcome type.

Data entered into summary tables by the Evidence Review Team were derived from the data extraction forms, evidence tables, and/or the articles. All summary tables were reviewed by the Work Group members.

Within each outcome section of each table, studies are ordered first by methodological quality (best to worst), then by applicability (most to least), and then by study size (largest to smallest). Results are presented by using the appropriate metric or summary symbols, as defined in the table footnotes.

Systematic Review Topics, Study Eligibility Criteria

The topics covered by systematic review are listed in Table 59 of the original guideline document. Predefined eligibility criteria are included. These were based on the study designs of the available literature (e.g., whether there were an "adequate" number of randomized trials) and the volume of the literature (e.g.,

whether there were "so many" studies that restriction based on such factors as study size or duration were deemed appropriate).

Grading of Individual Studies

Study Size and Duration

The study (sample) size is used as a measure of the weight of the evidence. In general, large studies provide more precise estimates of effects and associations. In addition, large studies are more likely to be generalizable; however, large size alone does not guarantee applicability. A study that enrolled a large number of selected patients may be less generalizable than several smaller studies that included a broad spectrum of patient populations. Similarly, longer duration studies may be of better quality and more applicable, depending on other factors.

Applicability

Applicability (also known as generalizability or external validity) addresses the issue of whether the study population is sufficiently broad so that the results can be generalized to the population of interest. The study population typically is defined primarily by the inclusion and exclusion criteria. The target population varied somewhat from topic to topic, but generally was defined to include patients with both chronic kidney disease (CKD) and diabetes (ideally diabetic kidney disease [DKD], CKD caused directly by diabetes mellitus). More specific criteria were sometimes appropriate, for example, subjects with retinopathy or pregnant women. A designation for applicability was assigned to each article, according to a 3-level scale. In making this assessment, sociodemographic characteristics were considered, as well as comorbid conditions and prior treatments. Applicability is graded in reference to the population of interest for each topic.

Results

In general, the result is summarized by both the direction and strength of the association. Depending on the study type, the results may refer either to dichotomous outcomes, such as the presence of retinopathy or a laboratory test above or below a threshold value, or to the association of continuous variables with outcomes, such as serum laboratory tests. The Work Group accounted for the magnitude of the association and both the clinical and statistical significance of the associations. Criteria for indicating the presence of an association varied among predictors depending on their clinical significance. Both univariate and multivariate associations are presented, when appropriate. The following metrics were used: prevalence, relative effects (relative risk [RR], odds ratio [OR], hazard ratio [HR], or net change—change from baseline in the intervention group minus the change in the control group), correlation (r or r^2), and test accuracy (sensitivity, specificity, and positive and negative predictive value). The choice of metric often was limited by the reported data. For some studies, only the statistical significance was reported.

Methodological Quality

Methodological quality (or internal validity) refers to the design, conduct, and reporting of the clinical study. Because studies with a variety of types of design were evaluated, a 3-level classification of study quality was devised:

- Least bias; results are valid. A study that mostly adheres to the commonly held concepts of high quality, including the following: a formal study; clear description of the population and setting; clear description of an appropriate reference standard; proper measurement techniques; appropriate statistical and analytical methods; no reporting errors; and no obvious bias. Not retrospective studies or case series.
- Susceptible to some bias, but not sufficient to invalidate the results. A study that does not meet all the criteria in category above. It has some deficiencies but none likely to cause major bias.
- Significant bias that may invalidate the results. A study with serious errors in design or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

Summarizing Reviews and Selected Original Articles

Work Group members had wide latitude in summarizing reviews and selected original articles for topics that were determined not to require a systemic review of the literature. However, a thorough review and summary of systematic reviews of diabetes and health education was performed.

Grading the Strength of Evidence

The strength of evidence was graded using a rating system as described in the section titled "Rating Scheme for the Strength of the Evidence."

Specific criteria for assessing the quality of the body of evidence (including an initial categorization of evidence quality based on study designs of the available studies) were discussed with the Work Group. For questions of interventions, quality was High, if randomized controlled trials; Low, if observational studies; Very Low, if other types of evidence. The quality rating was then decreased if there were serious limitations to individual study quality, if there were important inconsistent results across studies, if the applicability of the studies to the population of interest was limited, if the data were imprecise or sparse, or if there was thought to be a high likelihood of bias. The quality rating for observational studies was increased if there was strong evidence of an association (i.e., significant relative risk (RR) or odds ratio (OR) of about >2 [or <0.5] based on consistent evidence from 2 or more observational studies, with no plausible confounders), if there was evidence of a dose-response gradient, or if plausible confounders would have reduced the effect. Four final quality categories were used: High, Moderate, Low, and Very Low.

The Work Group and Evidence Review Team also discussed how the strength of the evidence would be determined based on the quality of evidence across all outcomes of interest, taking into account the relative importance of each of the outcomes (e.g., death and CKD progression having greater weight than albuminuria or glucose levels) and a balance between net benefits and additional considerations, such as costs (resource utilization), feasibility, availability, likely differences in patient values, likely differences among populations and regions.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Creation of Groups

The Chair and Co-Chair of the KDOQI™ Advisory Board selected the Co-Chairs of the Work Group and the Director of the Evidence Review Team, who then assembled groups to be responsible for the development of the guidelines. The Work Group and the Evidence Review Team collaborated closely throughout the project.

The Work Groups consisted of domain experts, including individuals with expertise in adult and pediatric nephrology, adult and pediatric diabetology and endocrinology, cardiology, pharmacology, social work, nursing, and nutrition. The first task of the Work Group members was to define the overall topics and goals of the guidelines. They then further developed and refined each topic, literature search strategies, and data extraction forms. The Work Group members were the principal reviewers of the literature; from their reviews and detailed data extractions, they summarized the available evidence and took the primary roles of writing the guidelines and rationale statements. Completed data extractions were shared among Work Group members.

The Evidence Review Team consisted of nephrologists, physician-methodologists, and research assistants from Tufts-New England Medical Center with expertise in systematic review of the medical literature. They supported the Work Groups in refining the topics and clinical questions so that literature searches could be undertaken. They also instructed the Work Group members in all steps of systematic review and critical literature appraisal. The Evidence Review Team coordinated the methodological and analytical process of the report, defined and standardized the methodology of performing literature searches, of data extraction and of summarizing the evidence in summary tables. They performed literature searches, organized abstract and article screening, created forms to extract relevant data from articles, organized Work Group member data extraction, and tabulated results. Throughout the project the Evidence Review Team led discussions on systematic review, literature searches, data extraction, assessment of quality and applicability of articles, evidence synthesis, and grading of the quality of the body of evidence and the strength of guideline recommendations.

Refinement of Guideline Topics and Development of Materials

The goals of the Work Group spanned a diverse group of topics, which would have been too large for a comprehensive review of the literature. Based on their expertise, members of the Work Group focused on specific questions deemed clinically relevant and amenable to systematic review. Other sources of data included previously published guidelines and systematic reviews. The Work Groups and Evidence Review Team developed: (1) draft guideline statements, (2) draft rationale statements that summarized the expected pertinent evidence, and

(3) data extraction forms requesting the data elements to be retrieved from the primary articles. The topic refinement process began before literature retrieval and continued through the process of reviewing individual articles.

Rating the Strength of Guidelines

Each major item of evidence discussed in the Rationale sections for each clinical practice guideline (CPG) and clinical practice recommendation (CPR) was given a strength rating. Upon consideration of the strength of evidence for the various sections of the body of evidence for a given set of recommendation statements, a determination was made whether the set of statements rise to the level of a CPG or whether the body of evidence is sufficiently weak to warrant only a CPR. Sets of statements that were graded as being Strong or Moderately Strong were designated as Guidelines. In the absence of strong or moderately strong quality evidence or when additional considerations did not support strong or moderately strong evidence-based recommendations, the Work Group could elect to issue expert opinion based recommendations termed CPRs. These recommendations are based on the consensus of the Work Group that the practice might improve health outcomes. As such, the Work Group recommends that clinicians consider following the recommendation for eligible patients. These recommendations are based on either weak evidence or on the opinions of the Work Group.

In addition, the Work Group adopted a convention for using existing expert guidelines issued for populations other than the target population. Grades for the strength of evidence assigned by the professional societies that issued the guidelines were adopted. When the guideline or the evidence was not graded, this Work Group assumed that the guideline would be based on at least moderately strong evidence. The extrapolation of these guideline recommendations from the general populations to the target population was considered to support grade B recommendations.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Rating the Strength of Guideline and Clinical Practice Recommendation (CPR) Statements

A It is strongly recommended that clinicians routinely follow the guideline for eligible patients. There is strong evidence that the practice improves health outcomes.

B It is recommended that clinicians routinely follow the guideline for eligible patients. There is moderately strong evidence that the practice improves health outcomes.

C (CPR) It is recommended that clinicians consider following the CPR for eligible patients. This recommendation is based on either weak evidence or on the opinions of the Work Group and reviewers that the practice might improve health outcomes.

Health outcomes are health-related events, conditions, or symptoms that can be perceived by individuals to have an important effect on their lives. Improving health outcomes implies that benefits outweigh any adverse effects.

COST ANALYSIS

The guideline developers reviewed published cost analyses.

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups
External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The Work Group appreciates the careful review of the draft guidelines and suggestions for improvement by external reviewers. Each comment was carefully considered and, whenever possible, suggestions for change were incorporated into the final report. As a result, the KDOQI™ (Kidney Disease Outcomes Quality Initiative™) Clinical Practice Guidelines and Clinical Practice Recommendations for Diabetes and Chronic Kidney Disease is the product of the Work Group, the Evidence Review Team, the National Kidney Foundation (NKF), and all those who contributed their effort to improve the Guidelines.

A list of individuals who provided written review of the draft guidelines can be found in the original guideline document.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions for the strength of each guideline (A, B, or C [CPR]), based on the quality of the supporting evidence as well as additional considerations, are provided at the end of the "Major Recommendations" field.

Clinical Practice Guidelines (CPGs) for Diabetes and Chronic Kidney Disease (CKD)

Guideline 1: Screening and Diagnosis of Diabetic Kidney Disease (DKD)

CKD in patients with diabetes may or may not represent DKD. In the absence of an established diagnosis, the evaluation of patients with diabetes and kidney disease should include investigation into the underlying cause(s).

1.1 Patients with diabetes should be screened annually for DKD. Initial screening should commence:

- 5 years after the diagnosis of type 1 diabetes; (A) or
- From diagnosis of type 2 diabetes. (B)

1.1.1. Screening should include:

- Measurements of urinary albumin-creatinine ratio (ACR) in a spot urine sample; (B)
- Measurement of serum creatinine and estimation of glomerular filtration rate (GFR). (B)

1.2 An elevated ACR should be confirmed in the absence of urinary tract infection with 2 additional first-void specimens collected during the next 3 to 6 months. (B)

- Microalbuminuria is defined as an ACR between 30-300 mg/g.
- Macroalbuminuria is defined as an ACR >300 mg/g.
- 2 of 3 samples should fall within the microalbuminuric or macroalbuminuric range to confirm classification.

1.3 In most patients with diabetes, CKD should be attributable to diabetes if:

- Macroalbuminuria is present; (B) or
- Microalbuminuria is present
  - In the presence of diabetic retinopathy (B)
  - In type 1 diabetes of at least 10 years' duration (A)

1.4 Other cause(s) of CKD should be considered in the presence of any of the following circumstances: (B)

- Absence of diabetic retinopathy
- Low or rapidly decreasing GFR
- Rapidly increasing proteinuria or nephrotic syndrome
- Refractory hypertension
- Presence of active urinary sediment
- Signs or symptoms of other systemic disease; or
- >30% reduction in GFR within 2-3 months after initiation of an angiotensin-converting enzyme (ACE) inhibitor or angiotensin-receptor blocker (ARB).

Guideline 2: Management of Hyperglycemia and General Diabetes Care in CKD

Hyperglycemia, the defining feature of diabetes, is a fundamental cause of vascular target-organ complications, including kidney disease. Intensive treatment of hyperglycemia prevents DKD and may slow progression of established kidney disease.

2.1 Target hemoglobin A_{1c} (HbA_{1c}) for people with diabetes should be <7.0%, irrespective of the presence or absence of CKD. (A)

Guideline 3: Management of Hypertension in Diabetes and CKD

Most people with diabetes and CKD have hypertension. Treatment of hypertension slows the progression of CKD.

3.1 Hypertensive people with diabetes and CKD stages 1-4 should be treated with an ACE inhibitor or an ARB, usually in combination with a diuretic. (A)

3.2 Target blood pressure in diabetes and CKD stages 1-4 should be <130/80 mmHg. (B)

Guideline 4: Management of Dyslipidemia in Diabetes and CKD

Dyslipidemia is common in people with diabetes and CKD. The risk of cardiovascular disease (CVD) is greatly increased in this population. People with diabetes and CKD should be treated according to current guidelines for high-risk groups.

4.1 Target low-density lipoprotein cholesterol (LDL-C) in people with diabetes and CKD stages 1-4 should be <100 mg/dL; <70 mg/dL is a therapeutic option. (B)

4.2 People with diabetes, CKD stages 1-4, and LDL-C $\geq$100 mg/dL should be treated with a statin. (B)

4.3 Treatment with a statin should not be initiated in patients with type 2 diabetes on maintenance hemodialysis therapy who do not have a specific cardiovascular indication for treatment. (A)

Guideline 5: Nutritional Management in Diabetes and CKD

Management of diabetes and CKD should include nutritional intervention. Dietary modifications may reduce the progression of CKD.

5.1 Target dietary protein intake for people with diabetes and CKD stages 1-4 should be the recommended daily allowance (RDA) of 0.8 g/kg body weight per day. (B)

Clinical Practice Recommendations (CPRs) for Diabetes and Chronic Kidney Disease

Clinical Practice Recommendation 1: Management of Albuminuria in Normotensive Patients With Diabetes and Albuminuria as a Surrogate Marker

Treatments that lower urinary albumin excretion may slow progression of DKD and improve clinical outcomes, even in the absence of hypertension. However, most people with diabetes and albuminuria have hypertension; management of hypertension in these patients is reviewed in Guideline 3.

1.1 Normotensive people with diabetes and macroalbuminuria should be treated with an ACE inhibitor or an ARB. (C)

1.2 Treatment with an ACE inhibitor or an ARB may be considered in normotensive people with diabetes and microalbuminuria. (C)

1.3 Albuminuria reduction may be considered a treatment target in DKD. (C)

Clinical Practice Recommendation 2: Multifaceted Approach to Intervention in Diabetes and CKD

Multiple risk factors are managed concurrently in patients with diabetes and CKD, and the incremental effects of treating each of these risk factors appear to add up to substantial clinical benefits.

2.1 The care of people with diabetes and CKD should incorporate a multifaceted approach to intervention that includes instruction in healthy behaviors and treatments to reduce risk factors. (C)

2.2 Target body mass index (BMI) for people with diabetes and CKD should be within the normal range (18.5-24.9 kg/m^2). (C)

Clinical Practice Recommendation 3: Diabetes and CKD in Special Populations

The increasing incidence of diabetes in children, young adults, the elderly, and members of disadvantaged and transitional populations is responsible for an increasing incidence of DKD in these groups. Racial/ethnic differences in susceptibility to DKD also may play a role. In pregnant women, the presence of diabetes and CKD may adversely affect the health of both the mother and her offspring.

3.1 Screening and interventions for diabetes and CKD should focus on populations at greatest risk. (C)

3.2 Although management of diabetes and CKD in special populations should follow the same principles as management in the majority population, there are special considerations in the treatment of children, adolescents, and the elderly. (C)

3.3 Population-based interventions may be the most cost-effective means for addressing the burden of CKD in special populations. Implementation and evaluation of population-based interventions should take into account the heterogeneity of the populations at risk. (C)

3.4 Specialists in high-risk pregnancy and kidney disease should co-manage pregnancy in women with diabetes and CKD. (C)

3.5 Treatment of DKD with renin-angiotensin system (RAS) inhibitors before pregnancy may improve fetal and maternal outcomes, but these medicines should be discontinued as soon as a menstrual period is missed or after a positive pregnancy test. (C)

3.6 Insulin should be used to control hyperglycemia if pharmacological therapy is necessary in pregnant women with diabetes and CKD. (C)

Clinical Practice Recommendation 4: Behavioral Self-Management in Diabetes and CKD

Behavioral self-management in patients with diabetes and CKD is particularly challenging because of the intensive nature of the diabetes regimen. Education alone is not sufficient to promote and sustain healthy behavior change, particularly with such a complex regimen.

4.1 Self-management strategies should be key components of a multifaceted treatment plan with attention to multiple behaviors: (C)

- Monitoring and treatment of glycemia
- Blood pressure
- Nutrition
- Smoking cessation
- Exercise
- Adherence to medicines

Definitions:

Rating the Strength of Guideline and Clinical Practice Recommendation (CPR) Statements

A It is strongly recommended that clinicians routinely follow the guideline for eligible patients. There is strong evidence that the practice improves health outcomes.

B It is recommended that clinicians routinely follow the guideline for eligible patients. There is moderately strong evidence that the practice improves health outcomes.

C (CPR) It is recommended that clinicians consider following the CPR for eligible patients. This recommendation is based on either weak evidence or on the opinions of the Work Group and reviewers that the practice might improve health outcomes.

Health outcomes are health-related events, conditions, or symptoms that can be perceived by individuals to have an important effect on their lives. Improving health outcomes implies that benefits outweigh any adverse effects.

Rating the Quality of Evidence

The strength of evidence was graded using a rating system that primarily takes into account: (1) the methodological quality of the studies; (2) whether the studies were carried out in the target population (i.e., patients with chronic kidney disease and diabetes, or in other populations) and (3) whether the studies examined health outcomes directly, or examined surrogate measures for those outcomes (e.g., reducing death or improving albuminuria). These 3 separate study characteristics were combined to provide a preliminary strength of evidence provided by pertinent studies. In addition, aspects of the GRADE recommendations for grading the quality of evidence and the strength of recommendations were incorporated to determine a final strength of evidence.

		Methodological Quality

Outcome	Population	Well Designed and Analyzed (little, if any, potential bias)	Some Problems in Design and/or Analysis (some potential bias)	Poorly Designed and/or Analyzed (large potential bias)
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Health outcome(s)	Other than the target population	Moderately strong[c]	Moderately strong[d]	Weak[h]
Surrogate measure for health outcome(s)	Target population	Moderately strong[e]	Weak[f]	Weak[h]
Surrogate measure for health outcome(s)	Other than the target population	Weak[g]	Weak[g]	Weak[g,h]

Strong: [a]Evidence includes results from well-designed, well-conducted study/studies in the target population that directly assess effects on health outcomes.

Moderately Strong: [b]Evidence is sufficient to determine effects on health outcomes in the target population, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies; OR [c]evidence is from a population other than the target population, but from well-designed, well-conducted studies; OR [d]evidence is from studies with some problems in design and/or analysis; [e]OR evidence is from well-designed, well-conducted studies or surrogate endpoints for efficacy and/or safety in the target population.

Weak: [f]Evidence is insufficient to assess the effects on net health outcomes because it is from studies with some problems in design and/or analysis on surrogate endpoints for efficacy and/or safety in the target population; OR [g]the evidence is only for surrogate measures in a population other than the target population; OR [h]the evidence is from studies that are poorly designed and/or analyzed.

CLINICAL ALGORITHM(S)

A clinical algorithm "Screening for Microalbuminuria" is provided in the original guideline document.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate diagnosis and management of patients with diabetes and chronic kidney disease (CKD)

POTENTIAL HARMS

Side effects of medications

CONTRAINDICATIONS

CONTRAINDICATIONS

Metformin is contraindicated in patients with kidney dysfunction.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- These Clinical Practice Guidelines (CPGs) and Clinical Practice Recommendations (CPRs) are based upon the best information available at the time of publication. They are designed to provide information and assist decision making. They are not intended to define a standard of care and should not be construed as one. Neither should they be interpreted as prescribing an exclusive course of management.
- Variations in practice will inevitably and appropriately occur when clinicians take into account the needs of individual patients, available resources, and limitations unique to an institution or type of practice. Every health care professional making use of these CPGs and CPRs is responsible for evaluating the appropriateness of applying them in the setting of any particular clinical situation. The recommendations for research contained within this document are general and do not imply a specific protocol.

Guideline Limitations

See the "Limitations" sections for each guideline in the original guideline document for information on limitations of the available evidence.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Implementation is an integral component of the KDOQI™ process, and it accounts for the success of its past guidelines. The Kidney Learning System component of the National Kidney Foundation is developing implementation tools that will be essential to the success of these guidelines.

"Implementation Issues" relevant to each clinical practice guideline and clinical practice recommendation are discussed in the original guideline document.

IMPLEMENTATION TOOLS

Clinical Algorithm
Foreign Language Translations
Patient Resources

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

KDOQI. KDOQI clinical practice guidelines and clinical practice recommendations for diabetes and chronic kidney disease. Am J Kidney Dis 2007 Feb;49(2 Suppl 2):S12-154. [598 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

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GUIDELINE DEVELOPER(S)

National Kidney Foundation - Disease Specific Society

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The National Kidney Foundation (NKF) makes every effort to avoid any actual or potential conflicts of interest that may arise as a result of an outside relationship or a personal, professional, or business interest of a member of the Work Group.

Specifically, all members of the Work Group are required to complete, sign, and submit a Disclosure Questionnaire showing all such relationships that might be perceived as real or potential conflicts of interest. All affiliations are published in their entirety at the end of this publication in the Work Group members' biographical sketch and are on file at the NKF.

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GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the National Kidney Foundation (NKF) Web site.

Print copies: Available from the National Kidney Foundation (NKF), 30 East 33rd St., New York, NY 10016. These guidelines are also available on CD-ROM from NKF.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Chronic kidney disease and diabetes: a new tool to break the cycle

These materials are available by contacting: National Kidney Foundation 30 East 33rd Street, New York, NY 10016 (phone: 212.889.2210 or 800.622.9010 or fax: 212.686.8916).

PATIENT RESOURCES

The following are available:

- Diabetes and chronic kidney disease (stages 1-4) (also available in Spanish)
- Diabetes and chronic kidney disease (stage 5) (also available in Spanish)
- Diabetes and chronic kidney disease: a guide for American Indians and Alaska natives
- Quality of life with diabetes and CKD
- Chronic kidney disease and diabetes: a new tool to break the cycle

These patient education materials are available by contacting: National Kidney Foundation 30 East 33rd Street, New York, NY 10016 (phone: 212.889.2210 or 800.622.9010 or fax: 212.686.8916).

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